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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CHRISTIAN KERSTEN, MARTE GRØNLIE CAMERON, and SVEIN MJÅLAND

Appeal 2020-001598
Application 14/128,232
Technology Center 1600

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and JOHN G. NEW, *Administrative Patent Judges*.

KATZ, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant[1] seeks our review,[2] under 35 U.S.C. § 134(a), of the Examiner's decision to reject claims 15 and 32–36, all of the pending claims in the application. Claims 1–14, 16–31, 37 and 38 have been cancelled. We have jurisdiction under 35 U.S.C. § 6(b). We REVERSE.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the Real Party in Interest as Sykehuset Sørlandet HF. (*See* Appeal Br. 3.)

[2] We consider the Specification dated December 20, 2013 ("Spec."), Final Office Action issued January 2, 2019 ("Final Act."), the Appeal Brief filed June 28, 2019 ("Appeal Br."), the Examiner's Answer issued October 23, 2019 ("Ans."), and the Reply Brief filed December 19, 2019 ("Reply Br.").

INTRODUCTION

Appellant's Specification provides methods of administering epidermal growth factor receptor ("EGFR") inhibitors to treat neuropathic pain. (Spec. 9:10–14.) The Specification defines neuropathic pain as a "complex, chronic pain state that usually is accompanied by tissue injury," that may include complex regional pain syndrome types I and II, trigeminal neuralgia, phantom pain, and diabetic neuropathy. (*Id.* at 4:23–27.) The Specification discloses that neuropathic pain responds poorly to standard pain treatments, such as non-steroidal anti-inflammatory drugs or opioids, and can lead to serious disability. (*Id.* at 1:32–2:14.)

The Specification discloses that activating mitogen-activated protein kinase ("MAPK")-signaling pathways is associated with neurological diseases and neuropathic pain. (*See id.* at 8:29–30.) For example, EGF-MAPK-signaling can be activated in neurons and glial cells in response to injury or dysfunction. (*See id.* at 8:10–11.) The Specification discloses that inhibiting EGFR may interrupt a negative feedback loop, thereby alleviating symptoms from neurological disorders, especially neuropathic pain. (*See id.* at 8:11–14.)

Appellant's claim 1 recites[3]:

> A method of treating a human subject that does not have cancer or has not been previously treated for cancer to relieve a neuropathic pain condition selected from the group consisting of phantom limb pain, complex regional

[3] Claim 1 has been modified by adding indentations.

> pain syndrome I, complex regional pain syndrome II, trigeminal neuralgia, diabetic neuropathy, comprising
>
> administering an agent that inhibits EGFR polypeptide to a subject exhibiting symptoms of said neuropathic pain condition,
>
> wherein said subject is not receiving opioid therapy and
>
> said administering reduces, modulates or eliminates said neuropathic pain condition and
>
> said agent is selected from the group consisting of cetuximab, panitumumab, afatinib, erlotinib, gefitinib, lapatinib, and neratinib.

(Appeal Br. 10.)

The Examiner rejects the claims as anticipated by Gutstein.[4] (*See* Final Act. 3–4.) The Examiner also rejects the claims for nonstatutory double patenting over claims 1–4, 6–8, 10–26, 28–30, and 32 of Application 15/270,525, now issued as U.S. Patent 10,611,844 B2. (*See* Final Act. 8–10.)

ANALYSIS

Anticipation by Gutstein

The Examiner finds that Gutstein discloses a method of administering a therapeutically effective amount of an EGFR modulator alone or in combination with an opioid to treat chronic pain and reduce opioid

[4] Gutstein, PCT Publication WO 2009/048947 A1, published April 16, 2009.

tolerance. (*See* Ans. 3.) The Examiner finds further that Gutstein discloses chronic pain includes neuropathic pain, such as, phantom limb pain, complex regional pain syndrome, diabetic neuropathy, and trigeminal neuralgia. (*See id.* at 4.) The Examiner finds that Gutstein discloses treating "uniquely human diseases" and thus, implicitly supports treating humans. (*Id.* at 3.) Finally, the Examiner finds that Gutstein discloses EGFR inhibitors include anti-EGFR antibodies, such as cetuximab, panitumumab, zalutumumab, nimotuzumab and matuzumab, and small molecule antagonists, such as erlotinib and lapatinib. (*See id.*)

Appellant contends that Gutstein does not enable the use of EGFR inhibitors to modulate or eliminate the specifically listed neuropathic pain conditions in the absence of opioid therapy. (*See* Appeal Br. 4–5.) According to Appellant, Gutstein does not enable one of ordinary skill in the art to make the invention without undue experimentation in view of the *Wands* factors. *See In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). Applying the factors, Appellant contends that: (1) the prior art recognizes that neuropathic pain is notoriously difficult to treat in humans, (2) a high quantity of experimentation would be needed to treat human neuropathic pain; (3) Gutstein does not provide guidance of EGFR monotherapy for treating neuropathic pain; and (4) Gutstein does not provide any dosage for any EGFR inhibitor administered as monotherapy. (*See* Appeal Br. 7–8, *see also* Reply Br. 7–15.)

Appellant contends further that Gutstein's working Examples 1 and 3 show that administering EGFR inhibitor alone does not provide an analgesic

effect. (Appeal Br. 6.) Appellant submits the Declaration of Dr. Michaelis,[5] who states that Gutstein's Example 3 indicates "that the EGFR inhibitor gefitinib, when administered alone, is not analgesic in a neuropathic pain model." (Michaelis Decl. ¶ 4.) Dr. Michaelis states that a person of ordinary skill in the art would have concluded that Gutstein's negative results for gefitinib indicates that "other EGFR inhibitors (such as cetuximab, panitumumab, afatinib, erlotinib, lapatinib, and neratinib which are specifically listed in the claims) . . . would not be effective to relieve neuropathic pain in the absence of opioid therapy." (*Id.* ¶ 6.) Accordingly, Appellant argues that Gutstein does not sufficiently enable a person of ordinary skill in the art to relieve neuropathic pain in the absence of opioid therapy. (Reply Br. 15, citing *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1382 (Fed. Cir. 2006).)

The Examiner responds that Gutstein only disparages gefitinib, and does not discourage using one of the other disclosed EGFR inhibitors to treat neuropathic pain. (Ans. 6–7.) The Examiner finds that there is no evidence in the art that the other EGFR inhibitors would not be capable of treating neuropathic pain. (*Id.* at 7.) Accordingly, the Examiner finds that "only the specific embodiment of gefitinib would be allowable over . . . Gutstein." (*Id.*)

We are persuaded by Appellant's argument that Gutstein does not disclose a method of administering an EGFR inhibitor without an opioid that "reduces, modulates or eliminates" a neuropathic pain condition in a human

[5] Declaration of Dr. Martin Michaelis dated August 7, 2018. ("Michaelis Decl.")

subject. Because anticipation requires a showing of each limitation of a claim in a single reference, we do not sustain the Examiner's rejection as discussed below. *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001).

In *Ben Venue Labs.,* our reviewing court found that claims directed to a method of administering specific amounts of an anti-cancer agent were anticipated by a prior art reference which disclosed the same method, although without achieving an anti-cancer effect. *See id.* at 1378. Our reviewing court held that the prior art anticipated the claims at issue despite disclosing a "failed experiment." *See id.* Accordingly, we do not agree with Appellant that Gutstein's Examples are dispositive on the issue of enablement, merely because they show that gefitinib alone was ineffective in treating neuropathic pain. We note that Appellant's own examples include two failed experiments of treating neuropathic pain with cetuximab (Case 1) and panitumumab (Case 2), compared to two positive experiments of administering cetuximab then gefitinib (Cases 2 and 3). (*See* Spec. 24:12–26:2.) Despite these failed experiments, Appellant's claims require administering panitumumab or other non-tested compounds. (*Contra* Michaelis Decl. ¶ 6.)

Nevertheless, we find that Gutstein simply does not teach each and every element as set forth in the claim either expressly or inherently. *See Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Appellant's claim 1 recites a particular result, namely "reduces, modulates, or eliminates said neuropathic pain condition," but Gutstein does not teach

this result. Rather, Gutstein teaches that gefitinib, when administered alone, is *not* analgesic in a neuropathic pain model.

In *Ben Venue Labs.*, our reviewing court determined that the claims at issue only required administering specific amounts of the therapeutic compound and not achieving a particular result. 246 F.3d at 1378 ("Kris enabled the performance of those steps even though he did not achieve a favorable outcome, which was not a requirement of the claim.") In contrast, Appellant's claim 1 recites a particular result, namely "reduces, modulates, or eliminates said neuropathic pain condition." (Appeal Br. 10.) Accordingly, the particular result is a requirement of the claim, but that particular result is not disclosed by the prior art. *Cf. id.* Furthermore, the Examiner relies on Gutstein's implicit teaching of treating humans, in the absence of an explicit teaching or explanation of extrapolating a mouse model (Examples 1 and 3) to the appropriate dose or regimen for a human. Such implicit teaching does not meet the standard for anticipation. Because the prior art does not disclose all of the claimed requirements, we do not sustain the Examiner's rejection of the claims under 35 U.S.C. § 102.

Obviousness-type Double Patenting

The Examiner *provisionally* rejects claims 15 and 32–36 under the doctrine of obviousness-type double-patenting over claims 1–4, 6–8, 10–26, 28–30, and 32 of Application 15/270,525. (Final Act. 9.) After the Examiner's Answer in this appeal, Application 15/270,525 issued as U.S. Patent 10,611,844 B2. If prosecution should continue in the current

application, the Examiner may wish to revisit the rejection for obviousness-type double-patenting over the issued claims of U.S. Patent 10,611,844 B2.

Appellant does not substantively address the double-patenting rejection. (Appeal Br. 4.) Because the Examiner *provisionally* rejects the claims on the ground of obviousness-type double-patenting, we conclude that it is premature to address the provisional rejection. *See Ex parte Moncla*, Appeal No. 2009-006448 (PTAB June 22, 2010). Accordingly, we do not reach the Examiner's obviousness-type double patenting rejection.

CONCLUSION

Upon consideration of the record and for the reasons given, we do not sustain the Examiner's anticipation rejection.

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
15, 32–36	102	Gutstein		15, 32–36
15, 32–36	Obviousness-type double patenting	Claims 1–4, 6–8, 10–26, 28–30, 32 of Application No. 15/270,525	Not reached	Not reached
Overall Outcome				15, 32–36

REVERSED